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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,190	07/31/2001	Hiroki Moriyama	14821	3967

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EXAMINER	
JASTRZAB, KRISANNE MARIE	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,190	MORIYAMA, HIROKI	
	Examiner	Art Unit	
	Krisanne Jastrzab	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 9-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 9-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Applicant has indicated in the response of 11/15/2004, that the essential material referred to above, is actually present in the original disclosure of the instant application as filed. The Examiner maintains that the specification should then accordingly be corrected to remove the language implying an improper incorporation by reference, for purposes of clarity and completeness. The Examiner would point Applicant to MPEP 608.01 (p) for such authority.

The Examiner would maintain and emphasize that incorporation by reference of a foreign application or patent is not improper if the material being incorporated is ***not essential*** material, but it is improper for ***essential*** material. It is not required that

Applicant remove the incorporation by reference, just the portion of that reference to ***essential*** material.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 9-15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 2000-060791 (Abs and figs.). The abstract clearly recites the application of steam to the tray, which requires an autoclave, high pressure sterilization device. See also Fig.1 the tray configuration as well as an endoscope having an observation window.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 8-12 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malchesky '490 in view of Hight, III '751 and either Mönch U.S. patent No. 4,739,729 or Hauze U.S. patent No. 4,798,292.

Malchesky teaches containment of a lumened instrument with a positioning member for maintaining a predetermined bent configuration of the instrument with structure including a tray and lid, the tray having means therein to maintain the curved configuration of the instrument. Both the lid and tray, have means for the ingress and egress of sterilant, therein.

Hight, III teaches a pipe portion and a coiled portion for containment of an endoscope during sterilization in order to maintain the curved dimension of the device. Hight, III clearly teaches distal lengths inclusive of a few centimeters up to 200 cm (see column 3, lines 60-65), as well as maintaining the curvature of the receiving vessel to match that of the endoscope (see column 6, lines 20-25).

Both Mönch and Hauze teach the known and expected use of substantially similar containers for endoscope sterilization, in either liquid or autoclave environments, the autoclave constituting a high-pressure sterilization device. See column 3, lines 8-13 of Mönch or column 3, line 50 of Hauze.

It would have been obvious to one of ordinary skill in the art to arrange the positioning means of Malchesky such that they address the known and expected curved dimensions of lumened instruments such as endoscopes, those known dimension supported in the disclosure of Hight, III. It would further have been well within the

purview of one of ordinary skill in the art to use such a container in any effective sterilizing environment, including autoclaves as supported by both Mönch and Hauze.

Claims 1-3, 8-12 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillebrenner et al., '221 in view of Hight, III '751 and either Mönch U.S. patent No. 4,739,729 or Hauze U.S. patent No. 4,798,292.

Hillebrenner et al., teach the invention substantially as claimed having a tray with a lid configured with structure to contain an endoscope in a predetermined, curved configuration. The tray and lid are hinged and latched together and having handle means. See column 2, lines 40-48 and 55-68, column 3, lines 1-35, column 6, lines 10-15, 20-25 and 45-60, column 7, lines 64-68, and column 10, lines 58-68.

It would have been obvious to one of ordinary skill in the art to arrange the positioning means of Hillebrenner et al., such that they address the known and expected curved dimensions of instruments such as endoscopes, those known dimension supported in the disclosure of Hight, III. It would further have been well within the purview of one of ordinary skill in the art to use such a container in any effective sterilizing environment, including autoclaves as supported by both Mönch and Hauze.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malchesky and Hight, III as applied to claims 1-3, 8-12 and 14-15 above, and further in view of Morse '758.

Morse teaches that it is known and expected to store lumened instruments in either curved or straight configurations for sterilization (see column 2, lines 20-27).

It would have been obvious to one of ordinary skill in the art to position the means within the device of the combination above such as to accommodate the instrument in a straight configuration where the curve maintenance is not essential, as this configuration is recognized as equivalent.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillebrenner et al., together with Hight, III as applied to claims 1-3, 8-12 and 14-15 above, and further in view of Morse '758.

It would have been obvious to one of ordinary skill in the art to position the means within the device of the combination above such as to accommodate the instrument in a straight configuration where the curve maintenance is not essential, as this configuration is recognized as equivalent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 9-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 25-34 of copending Application No. 09894659. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are of the same inventive concept and in their current amended state both claim a sterilization tray for endoscopes having means to control the shape of the endoscope while contained and during sterilization without patentable distinction.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 1-3 and 9-15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krisanne Jastrzab
Primary Examiner
Art Unit 1744

March 1, 2006